

## **PAIN RELIEVER PLUS- acetaminophen, aspirin and caffeine tablet, film coated**

### **Major Pharmaceuticals**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Major 44-159B**

#### ***Active ingredients (in each tablet)***

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)\*

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

#### ***Purpose***

Pain reliever

Pain reliever

Pain reliever aid

#### ***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - premenstrual and menstrual cramps

#### ***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include:

- shock
- facial swelling
- hives
- asthma (wheezing)

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

#### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to this product or any of its ingredients

#### **Ask a doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- you are taking a diuretic

#### **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

#### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present

- new symptoms occur

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

***Directions***

- **do not take more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, croscopovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

***Questions or comments?***

**(800) 616-2471**

**Principal Display Panel**

**MAJOR®**

**Compare to the active ingredients in Excedrin® Extra Strength†**

NDC 0904-5135-59

**Pain Reliever Plus**

**Acetaminophen, Aspirin (NSAID), and Caffeine**

250 mg/250 mg/65 mg

**Pain Reliever / Pain Reliever Aid**

Actual Size

**100** Coated Tablets

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

†This product is not manufactured or distributed by GSK Consumer Healthcare S.A., owner of the registered trademark Excedrin®

Extra Strength. 50844 REV1119G15912

Distributed by: **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

M-17 Rev. 02/20

Re-order No. 252831



44-159B

## PAIN RELIEVER PLUS

acetaminophen, aspirin and caffeine tablet, film coated

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5135
Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)			ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)			ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)			CAFFEINE	65 mg
Inactive Ingredients				
Ingredient Name				Strength
CROSPVIDONE (UNII: 2S7830E561)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color		WHITE	Score	no score
Shape		ROUND	Size	11mm
Flavor			Imprint Code	44;159
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5135-59	1 in 1 CARTON	11/17/1992	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part343	11/17/1992	

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Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0904-5135)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0904-5135)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0904-5135)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0904-5135)

Revised: 2/2021

Major Pharmaceuticals